K071376

VERTEBRON™ PSS Pedicle Screw System
Special 510(k) Summary
May 2007

VIII. Summary of Safety and Effectiveness

JUN 19 2007

SUBMITTER:
VERTEBRON Inc.
400 Long Beach Blvd.
Stratford, CT 06615
(203) 380-9340

CONTACT PERSON:
Luis Nesprido
Senior Manager Regulatory Affairs

DATE PREPARED:
May 16, 2007

CLASSIFICATION NAME:
21 CFR §888.3050 Spinal Interlaminal Fixation Orthosis
21 CFR §888.3060 Spinal Intervertebral Fixation Orthosis
21 CFR §888.3070 Pedicle Screw Spinal System

COMMON NAME:
Pedicle Screw Spinal System

PROPRIETARY NAME:
VERTEBRON™ PSS Pedicle Screw System

PREDICATE DEVICES:
VERTEBRON™ PSS Pedicle Screw System – K033352, K043152 & K051716

DEVICE DESCRIPTION:
The VERTEBRON PSS Pedicle Screw System is comprised of non-sterile, single use, titanium alloy components. The VERTEBRON PSS Pedicle Screw System attaches to the vertebral body by means of screws to the non-cervical spinal and allows a surgeon to build a spinal implant construct. This system's design is intended to stabilize the spinal operative site during the fusion process of a bone graft in the disc space. The VERTEBRON PSS Pedicle Screw System is made up of rods, multi-axial and standard screws, hooks, locking caps and both adjustable and fixed cross connectors. This submission adds 5.5, 6.5 & 7.5mm Cannulated MA Screws & Buttress Cap.

INTENDED USE:
The VERTEBRON PSS Pedicle Screw System is intended for noncervical, nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or

lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients. The VERTEBRON PSS™ Pedicle Screw System is intended for non cervical pedicle fixation for the following indications: spondylolisthesis (Grade 3 and 4 at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment); trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

MATERIALS:

The material used is medical grade titanium material that conforms to ASTM F136.

SUBSTANTIAL EQUIVALENCE:

Testing in accordance with ASTM F1717 was performed and demonstrated that the VERTEBRON PSS™ Pedicle Screw System Cannulated MA Screws are substantially equivalent to the VERTEBRON PSS Pedicle Screw System (K033352, K043152 & K051716), which have received market clearance by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

VERTEBRON, Inc.
% Mr. Luis Nesprido
Senior Manager, Regulatory Affairs,
400 Long Beach Blvd.
Stratford, Connecticut 06615

JUN 13 2007

Re: K071376
Trade/Device Name: VERTEBRON PSS™ Pedicle Screw System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class III
Product Code: NKB, KWQ, KWP, MNH and MNI
Dated: May 16, 2007.
Received: May 17, 2007.

Dear Mr. Nesprido:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N.Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Mr. Luis Nesprido

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices and Radiological Devices	240-276-0120

Mr. Luis Nesprido

Indications for Use

510(k) Number (if known): K071376

Device Name: VERTEBRON PSS™ Pedicle Screw System

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Prescription Use ___x____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K071376